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July 28, 2020

VIA ECF

The Honorable Robert B. Kugler
United States District Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on July 29.

1. Plaintiff Fact Sheet Deficiencies – Show Cause Requests

First Time Listed – Remaining Core Deficiencies:

The following Plaintiff Fact Sheet ("PFS") contains core deficiencies which remain unresolved. Specifically, the below Plaintiff has failed to respond or provide a supplemental or amended fact sheet to address the alleged deficiencies. This is the first time this case has been listed on this agenda.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
1.	Townsend, James	19-cv-18407	Gillman Law, LLP	No response to any alleged deficiencies.	2/5/20

Second Listing Cases – Failure to File PFS:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are overdue. Each of these twelve (12) cases was previously listed on the agenda for the June 24, 2020 CMC (Dkt. 488-1). Moreover, Defendants provided this list to Plaintiffs' leadership counsel for distribution on July 23, 2020, and further followed up via email with individual Plaintiffs' counsel in the cases below on July 28, 2020, with additional notification that the underlying cases are overdue, have been listed on a prior agenda as deficient, and that Defendants would be requesting an order to show cause returnable at the August Case Management Conference with respect to these cases.

Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next Case Management Conference, as to why the case should not be dismissed.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due (60 days + SFC)
1.	Avedikian, Kevork	2019 -CV-06822	Levin Papantonio	Failed to File PFS	SFC: 9/19/19 PFS Due: 11/18/19
2.	Babin, Amanda	19-14649	Damon J. Baldone and Associates, APLC	Failed to File PFS	Original SFC- 1/24/20, 1st Am. SFC – 6/2/20 PFS Due: 3/24/20
3.	Cantrell, Marcia	2019-cv-14891	Golden Law Office	Failed to File PFS	SFC: 9/11/19 PFS Due: 11/10/19

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due (60 days + SFC)
4.	DeShields, Nettie	20-01030	Douglas & London	Failed to File PFS	SFC: 1/30/20 PFS: 3/30/20
5.	Dufrene, Lana	2019 - cv- 15633	Gainsburgh Benjamin	Failed to File PFS	SFC: 9/20/19 PFS Due: 11/19/19
6.	Fougere, Therese	19-17597	Law Offices of Pius A. Obioha & Associates, LLC	Failed to File PFS	SFC: 1/29/20 PFS Due: 3/29/20
7.	Jones, Philip	20-cv-2795	Douglas & London	Failed to File PFS	SFC: 3/13/20 PFS Due: 4/14/20
8.	Lasseigne, Beverly	2020 -CV- 03611	Law Offices of John D. Sileo LLC	Failed to File PFS	SFC: 4/3/20 PFS Due: 6/2/20
9.	Guillory Maxine,	2019 - CV- 10044	Levin Papantonio	Failed to File PFS	SFC: 9/19/20 PFS Due: 11/18/20
10.	Murray, Brian	2020 -CV- 01055	Levin Papantonio	Failed to File PFS	SFC :1/30/20 PFS Due: 3/30/20

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due (60 days + SFC)
11.	Pittman, Charleston	2019 -CV-15638	Law Offices of John D. Sileo LLC	Failed to File PFS	SFC: 4/3/20 PFS Due: 6/2/20
12.	Williams, Charles	2019 - CV- 07632	Levin Papantonio	Failed to File PFS	SFC: 9/20/19 PFS Due: 11/19/19

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the July 29 Case Management Conference.

2. Defendant Fact Sheets

Manufacturer Defendant Fact Sheets

The Court heard lengthy argument on the Manufacturer Defendant Fact Sheets ("Manufacturer DFS") on May 27, 2020, and spent over an hour carefully walking through the Manufacturer DFS, issuing rulings on all disputes, and ultimately approving the Manufacturer DFS. Defendants attach the Manufacturer DFS reflecting the Court's rulings as Exhibits A and B.

Following the Court's approval of the Manufacturer DFS, Plaintiffs have sought a significant modification. The version of the Manufacturer DFS approved at the May case management conference explains that no Defendant is obligated to complete a DFS relating to a given Plaintiff until that Plaintiff has served a *substantially completed and verified Plaintiff Fact Sheet*. Plaintiffs are seeking to alter the language of the introductory paragraph of the Manufacturer DFS to require the first Defendant in the supply chain to complete its DFS after a Plaintiff has served only a handful of items: (1) a PFS with Section I completed; (2) copies of prescription and/or pharmacy records demonstrating use of a valsartan-containing drug; and, for personal injury Plaintiffs (3) a signed HIPAA authorization form and medical records and/or a certification under oath demonstrating that he or she has been diagnosed with the injury claimed in the PFS. Though the Manufacturer DFS have been under negotiation for over a year, *see* Dkt. 160 (reporting to the Court that Defendants had received a draft DFS from Plaintiffs), Plaintiffs first suggested this significant modification on June 25, *after* these fact sheets had been put before the Court. *See* Dkt. 439. This dispute regarding the information that a Plaintiff must provide to trigger any Defendant's obligation to complete a Defendant Fact Sheet currently affects Defendants throughout the supply chain and implicates the Manufacturer DFS, Wholesaler DFS, and Retail Pharmacy DFS.

Plaintiffs' new proposal should be rejected, and no Defendant should be obligated to complete a DFS until a given Plaintiff has served a substantially complete, verified PFS.

First, failure to respond to the complete PFS leaves Defendants without key information necessary to answer their DFS. For example, Item II.I on the API Manufacturer DFS requires the responding API Manufacturer to supply information "only if Plaintiff III.B.7 in the PFS." With only Section I of the PFS completed and certain documentation provided, a Defendant would be unable to determine whether it is obligated to respond to Item II.I. The DFS was negotiated with the understanding that it would be completed once a substantially completed PFS had been received, and altering this requirement would necessitate revisiting previously-resolved disputes.

Moreover, completing these fact sheets will be a significant undertaking for Defendants. Manufacturers[1], along with wholesalers and retailer pharmacies (to the extent named) are obligated to complete a DFS for each named class representative, as well as for twenty additional Plaintiffs under the Court's January 30, 2020 Order. Dkt. 360. In each instance, Defendants from multiple levels of the supply chain are expected to complete a DFS. Plaintiffs' proposal would obligate Defendants to complete a DFS even where Plaintiffs have put minimal effort into their submissions, and would even apply this obligation where a given Plaintiff skips over entire sections of its PFS, leaving Defendants without critical information necessary to assess that Plaintiff's claims. Completing all DFS relating to a particular Plaintiff is expected to consume significant Defendant resources, and the obligation to complete these DFS should only be applied after Plaintiffs have complied with their own obligation to provide substantially completed versions of the agreed Plaintiff Fact Sheets.

Retail Pharmacy Defendant Fact Sheets

The Retail Pharmacy Defendants (the "Pharmacy Defendants") join in the Manufacturer Defendants' and Wholesaler Defendants' objections to Plaintiffs' proposal regarding the "substantially complete" language in the DFS. Following several meet and confers with Plaintiffs, the Pharmacy Defendants otherwise appear to have reached an agreement with Plaintiffs regarding the overall scope and substance of the remaining portions of the DFS, and the Pharmacy Defendants are working with Plaintiffs' counsel to finalize the DFS language reflecting their agreement.

Wholesaler Defendant Fact Sheets

The Parties have engaged in several meet and confer conferences and substantial negotiations regarding the DFS applicable to Wholesaler Defendants ("Wholesaler DFS"), including up to and through today. Agreement on the majority of a Wholesaler DFS has been reached, and attached as Exhibit C is a copy of the most recent draft of their proposed DFS. In

[1] While there is no FDA liaison-specific DFS, the API and Finished Dose Manufacturers will obtain information from FDA liaisons to the extent necessary to complete their DFS.

addition to the universal dispute regarding the "substantially complete" language proposed by Plaintiffs in each DFS, discussed above, in the attached draft DFS Wholesaler Defendants identify three specific issues regarding the Wholesaler DFS that require resolution by the Court.

1. Plaintiffs request Repackager and Relabeler Defendants be included in the DFS to Wholesalers. Wholesalers object to their inclusion, as counsel for Wholesalers do not represent those Defendants-and the Wholesaler DFS has not been negotiated on behalf of any of those Defendants or with the input of any of those Defendants. Additionally, Repackager and Relabeler Defendants are subject to the peripheral Defendant Case Management Order, and to the extent Plaintiffs believe a DFS is necessary with respect to any of those Defendants, including any currently dismissed Defendants Plaintiffs may later seek to bring back into the litigation, Plaintiffs should negotiate a DFS directly with those Defendants.

2. Plaintiffs request that, in response to questions about the purchase and sale of an "Affected Drug" (as defined in the Wholesaler DFS), a responding Wholesaler Defendant provide information about the price a Wholesaler paid the Manufacturer Defendant for the "Affected Drug" and the price a Wholesaler charged the Pharmacy Defendant for that "Affected Drug." Wholesaler Defendants object to providing any pricing information regarding an "Affected Drug," as Plaintiffs' request for that information has already been denied by the Court in its decision issued on the Wholesaler macro-discovery issues, which is applicable to and should guide the preparation of the DFS. Plaintiffs' repeated attempt to obtain that information in the context of a DFS - in contravention of the Court's prior order - is improper.

3. Plaintiffs' proposed request for return information is not focused on the facts associated with a particular Plaintiff at issue and instead seeks expansive information on returns, for any reason, that are irrelevant to a Plaintiff's case, including data on returns made long before a Plaintiff may have purchased their first "Affected Drug." Plaintiffs request that a Wholesaler Defendant provide information on all returns received from the pharmacy or pharmacies where an individual Plaintiff purchased an "Affected Drug" for a period of eight years (January 1, 2012 through December 31, 2019). Consistent with the purposes of the DFS, Wholesaler Defendants instead request that any information about returns of an "Affected Drug" provided in a DFS applicable to an individual Plaintiff's case be focused on returns received during the Relevant Time Period (as defined in the Wholesaler DFS), which focuses on the time period a Plaintiff actually took an "Affected Drug.

3. Short Form Complaints

As new Short Form Complaints are filed, Defendants continue to identify Short Form Complaints that have not been properly filed and served through MDL Centrality. Additionally, Defendants have identified several instances in which Plaintiffs bringing claims only for losartan-

related injuries have filed valsartan Short Form Complaints. The Parties are working together in an effort to resolve these issues without Court intervention.

4. Coordination of State Court Cases

At least ten additional valsartan cases have been filed in New Jersey Superior Court, Middlesex County, within the last thirty (30) days. These cases include:

Caption	Case Number	Assigned Judge
Rafuls v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4629-20	Hon. Patrick Bradshaw
Pedrick v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4616-20	Hon. Bruce Kaplan
Mooradian v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4603-20	Hon. Christoph Rafano
Franco v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4602-20	Hon. Christoph Rafano
Dessoye v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4614-20	Hon. Bruce Kaplan
Cardy v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4599-20	Hon. Christoph Rafano
Debose v. Zhejiang Huahai Pharmaceutical Co., Ltd. et al.	MID-L-4601-20	Hon. Christoph Rafano
Byrum v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4590-20	Hon. Thomas D. McCloskey
Wiltshire v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4593-20	Hon. Thomas D. McCloskey
Lippl v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	MID-L-4591-20	Hon. Thomas D. McCloskey

Plaintiffs have agreed to enter stipulated orders to hold the ten (10) recently-filed cases in abeyance. The Parties will work to finalize these orders and will provide the Court with an update on the status of these stipulations at the next case management conference.

In addition to these recently-filed cases, an additional three actions were previously filed in Middlesex County, New Jersey and are being held in abeyance by order of Judge Jamie D. Happas. These cases include:

Caption	Case Number	Assigned Judge
Orlowsky v. Prinston Pharmaceutical Inc., et al.	No. MID-L-0002554-19	Hon. J.R. Corman
Robertson v. Prinston Pharmaceutical Inc., et al.	No. MID-L-004228-19	Hon. Patrick Bradshaw
Garnes v. Zhejiang Huahai Pharmaceutical Co., Ltd.	No. MID-L-005191-19	Hon. Thomas D. McCloskey

In addition, two cases are currently pending in Illinois state court. These cases are:

Caption	Case Number	Assigned Judge
Shanov v. Walgreen Boots Alliance, Inc., et al.	No. 2020 CH 1884 (Cook Co.)	Hon. Anna Helen Demacopoulos
Maxton, et al v. Solco Healthcare U.S., et al.	No. 20-L-0530 (St. Clair Co.)	Not yet assigned

Defendants previously removed a case filed by Plaintiff Shanov to the U.S. District Court for the Northern District of Illinois. Plaintiff voluntarily dismissed the case before it could be transferred to this MDL. Plaintiffs' counsel then refiled a case in Illinois state court on February 14, 2020. Defendants have filed a motion to dismiss in the new *Shanov* matter. The *Maxton* case was filed on July 13, 2020. Defendants will continue to update the Court on the status of all known state court cases relating to valsartan, losartan, and irbesartan.

5. Schedule for General Causation

With ESI, paper discovery, and Rule 34 productions underway, this litigation is entering what the Court has recognized as a "transition phase." The parties have discussed the possibility of taking depositions of the putative class representatives before the end of the year and, on a parallel track, Defendants anticipate pursuing plaintiff-specific discovery on the personal-injury side. Additionally, the litigation has been pending well more than a year and Plaintiffs should be in a position by now to begin identifying their general causation theories with respect to the alleged cancers at issue.

To that end, Defendants submitted the attached letter to Plaintiffs on Friday, July 24 in order to begin negotiating a reasonable schedule for the orderly progression of general causation discovery. *See* Exhibit D. As Judge Kugler aptly noted at the outset of this MDL, "causation carries over" into all the cases, including the economic class actions, because "if the contamination is not dangerous," then there may not be any real economic injury. Indeed, this information is relevant not only to the personal-injury cases, but also to the medical-monitoring and economic class actions, and further delay of these issues will only impede the ultimate disposition of the MDL.

To allow discovery to progress as efficiently as possible, Defendants have requested that Plaintiffs first disclose the specific types of cancer for which they anticipate providing expert reports on the issue of general causation. By way of illustration, over 30 variations of cancer have been identified in Short Form Complaints as purportedly caused by alleged nitrosamine impurities in valsartan-containing medications. In fact, one case purports to involve "all classes of cancer." Similarly, the Master Personal Injury Complaint speaks generally of the "development of cancers," Dkt. 122 ¶ 2, while the Consolidated Amended Medical Monitoring Class Action Complaint refers to the non-specific "risk of developing cancer," Dkt. 123 ¶ 1. However, "even the strongest carcinogens don't raise the risk of all types of cancer." *See* American Cancer Society, *Determining if Something is a Carcinogen*, found at *https://www.cancer.org/cancer/cancer-causes/general-info/determining-if-something-is-a-carcinogen.html*. Put differently, cancer is "a heterogeneous disease" and therefore it "is inconceivable that a pharmaceutical agent should act as a universal carcinogen, as not even strong carcinogens, such as tobacco smoking and radiation, are universally carcinogenic." Pottegard, et al., *Basic Clin. Pharmacol. Toxicol.* (2018). Thus, when evaluating association and causation, "differentiation according to histological subtypes" must be employed. *Id.*

Notably, U.S. District Judge Robin Rosenberg, presiding over the *Zantac* MDL, recently entered the attached case management order requiring the plaintiffs to make this sort of disclosure by January 8, 2021—just 10 months after that MDL was formed. *See* Exhibit E.

Ultimately, Defendants envision the establishment of deadlines to allow general-causation issues to be litigated in an efficient, timely manner proceeding in certain stages which mirror what has been negotiated and implemented in *Zantac*. First, Plaintiffs disclose the types of cancer for which expert testimony will be provided. Second, Plaintiffs identify the disciplines and specializations of general-causation experts and areas of expertise relevant to each expert's general-causation expert report, with Defendants making a similar disclosure thereafter. Third, Plaintiffs serve their general-causation expert reports and produce their experts for deposition. Fourth, Defendants serve their general-causation expert reports and produce their experts for deposition. And, finally, the parties engage in *Daubert* motion practice, culminating in a hearing and the potential narrowing of key issues for trial and/or alternative resolution.

Defendants acknowledge that, having raised the issue on July 24, additional time is required for the parties to meet and confer on the specifics. Even so, Defendants wanted to take this opportunity to introduce the concept to the Court, and to discuss the overall timeframe for the

completion of the general causation process, and they look forward to engaging Plaintiffs in this process.

6. Teva's Motion to Enforce ESI Protocol/Parties' Negotiations on CMML

As the Court is well aware, the Teva Defendants and Plaintiffs have been engaged in extensive briefing and argument on the Teva Defendants' use of CMML throughout July. *See* Dkt. 513, 517, 526, 527; Trans. of July 15, 2020 Teleconference. The Teva Defendants refer to the arguments presented therein and will be prepared to address those in further detail as needed. However, Plaintiffs submitted an affidavit as an attachment to Plaintiffs' Letter Brief filed on July 24, 2020, which contains numerous statements requiring a response. Accordingly, the Teva Defendants have attached as Exhibit F the Declaration of Maura R. Grossman in Further Support of the Teva Defendants' Motion to Enforce ESI Protocol and Supplemental Letter Brief.

The Teva Defendants hope that many of these issues can be resolved during the meet and confer set for this afternoon, and look forward to discussing with Plaintiffs and the Court at that time.[2]

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Sarah Johnston, Esq. (*via email*)
Jeffrey Geoppinger, Esq. (*via email*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)

[2] Downstream Defendants do not currently anticipate the use of TAR but reserve the right to use TAR in the future if discovery requires.